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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,467	03/05/2004	Richard F. Wenstrom JR.	022956-256 (MIT-5027)	2466
21125 7590 12/03/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 12/03/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/708,467	Applicant(s) WENSTROM ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-18 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-18 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/08/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-12, 14-15 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (U.S. Patent No. 6,409,730).

Green et al. disclose a tunnel notcher and guidewire delivery device, comprising an elongate member (FIG. 1) with proximal and distal ends and an inner lumen (ref. #9) extending therebetween, the inner lumen being adapted to receive a guidewire; and a single cutting element disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being substantially wedge-shaped and extending radially outward from the elongate member. A distal portion of the distal end of the elongate member is substantially tapered. The cutting element is disposed proximal to the substantially tapered distal portion of the elongate member. The cutting element includes a distal-facing surface that is disposed at an acute angle with respect to a longitudinal axis of the elongate member. The angle between the cutting element and the longitudinal axis of the elongate member is less than 90°. The angle is in the range of about 20° to 70°. The cutting element includes a base portion coupled to the elongate member and a cutting edge positioned a distance

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apart from the elongate member. The cutting edge is positioned distal to the base portion. The cutting edge that is positioned a distance apart from the elongate member has a length that is less than a diameter of the elongate member. The cutting element is adapted to create a notch in bone having a substantially semi-circular shape. The device further comprising a handle (ref. #3) disposed on a proximal portion of the elongate member. The handle extends in a direction transverse to a longitudinal axis of the elongate member. The cutting element has a substantially wedge-shaped such that a width of the cutting element increases in a proximal to distal direction.

Claims 1-3, 5, 9-15 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Russin (U.S. 5,807,276).

Russin discloses a tunnel notcher and guidewire delivery device, comprising an elongate member with proximal (FIG. 3) and distal (FIG. 2) ends and an inner lumen (ref. #34) extending therebetween, the inner lumen being adapted to receive a guidewire; and a cutting element (ref. #72) disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being substantially wedge-shaped and extending radially outward from the elongate member. A distal portion of the distal end of the elongate member is substantially tapered (ref. #22, sharpened edge). The cutting element is disposed proximal to the substantially tapered distal portion of the elongate member. The cutting element includes a distal-facing surface that is disposed at an acute angle with respect to a longitudinal axis of the elongate member. The cutting element includes a base portion (ref. #68) coupled to the elongate member and a cutting edge positioned a

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distance apart from the elongate member. The cutting edge is positioned distal to the base portion. The cutting edge that is positioned a distance apart from the elongate member has a length that is less than a diameter of the elongate member. The cutting element is adapted to create a notch in bone having a substantially semi-circular shape. The device further comprising a plurality of indicia (at ref. #36) formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a bone tunnel. The device further comprising a handle (ref. #'s 3, 40) disposed on a proximal portion of the elongate member. The handle extends in a direction transverse to a longitudinal axis of the elongate member. The distal portion (FIG. 2) has a length greater than a length of the cutting element (ref. #72).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-15 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruppert (US 571,400) in view of Scholl (U.S. Patent No. 6,110,175).

Ruppert discloses a tunnel notcher comprising an elongate member (FIGS. 1-2) with proximal (top end) and distal (bottom end) ends, and a single cutting element (ref. #3) disposed proximal to the distal end of the elongate member and capable of

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removing bone within an opening of a bone tunnel, the cutting element being substantially wedge-shaped and extending radially outward from the elongate member. A distal portion (see FIG. 1 at ref. #2) of the distal end of the elongate member is substantially tapered. The cutting element is disposed proximal to the substantially tapered distal portion of the elongate member. The cutting element includes a distal-facing surface that is disposed at an acute angle with respect to a longitudinal axis of the elongate member. The distal-facing surface is substantially concave. The angle between the distally facing surface of the cutting element and the longitudinal axis of the elongate member is less than 90°. The angle is in the range of about 20° to 70°. The cutting element includes a base portion coupled to the elongate member and a cutting edge positioned a distance apart from the elongate member. The cutting edge is positioned distal to the base portion. The cutting edge that is positioned a distance apart from the elongate member has a length that is less than a diameter of the elongate member. The cutting element is capable of creating a notch in bone having a substantially semi-circular, arcuate shape. The width of the cutting element increases in a proximal to distal direction

Ruppert discloses the claimed invention except for (1) an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire (claim 1); (2) a handle extending in a direction transverse to a longitudinal axis of the elongate member disposed on a proximal portion of the elongate member (claims 14-15); and (3) a plurality of indicia formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a tunnel (claim 13).

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Scholl discloses (1) an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire, (2) and a handle extending in a direction transverse to a longitudinal axis of the elongate member disposed on a proximal portion of the elongate member, and (3) a plurality of indicia formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a tunnel, to provide a chisel for removing material that can assess impaction into the material and can be used with a guide wire.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Ruppert with an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire, (2) and a handle extending in a direction transverse to a longitudinal axis of the elongate member disposed on a proximal portion of the elongate member, and (3) a plurality of indicia formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a tunnel in view of Scholl to provide a chisel for removing material that can assess impaction into the bone and can be used with a guide wire.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruppert (US 571,400) in view of Scholl (U.S. Patent No. 6,110,175) further in view of Boucher et al. (US 5,658,289).

Ruppert and Scholl disclose the claimed invention except for and (4) a locking mechanism comprising a threaded member disposed within a threaded bore formed in a handle, the threaded bore being in communication with the inner lumen of the elongate

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member is formed on the handle mated to the proximal end of the elongate member (claims 16-18).

Boucher et al. discloses a locking mechanism comprising a threaded member (ref. 30) disposed within a threaded bore formed in a handle extending in a direction transverse to a longitudinal axis of the elongate member disposed on a proximal portion of the elongate member, the threaded bore being in communication with the inner lumen of the elongate member is formed on the handle mated to the proximal end of the elongate member to secure the guide wire.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Ruppert and Scholl with a threaded member disposed within a threaded bore formed in a handle, the threaded bore being in communication with the inner lumen of the elongate member is formed on the handle mated to the proximal end of the elongate member in view of Boucher et al. to secure the guide wire.

Response to Arguments

Applicant's arguments filed 06/17/2008 have been fully considered but they are not persuasive.

Applicant argues that the mere addition of the term "single" distinguishes the claims from the prior art. The examiner respectfully disagrees. The current claims neither state that the single cutting element is the "only" cutting element nor does that claim state "consisting of" (currently, the claim recites "comprising"). The mere addition

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of the term "single" without either adding "only" or "consisting of," or some other narrowing claim limitation, cannot overcome the prior art.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733